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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,276	12/03/2003	Wasimul Haque	12695.13USD2	1586

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P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER

SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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11/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/729,276

Applicant(s)

HAQUE ET AL.

Examiner

Phyllis G. Spivack

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8-10-07</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicants' Response filed August 10, 2007 is acknowledged. Claims 1 and 5-11 remain under consideration.

An Information Disclosure Statement filed August 10, 2007 is further acknowledged. All documents have been reviewed; however, non-published U.S. patent applications are not proper citations on U.S. patents.

In the last Office Action claims 1 and 5-11 were rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al., Stroke, in view of Goodman & Gilman. It was asserted Jacobs teaches an association between decreased levels of vitamin B₆ and an increased risk of ischemic stroke. The three forms of vitamin B₆ are pyridoxine, pyridoxal and pyridoxamine. Each of these compounds is readily converted in the liver of mammals to pyridoxal 5'-phosphate. Jacobs teaches a deficiency in the vitamin to be a finding that is highly correlated to a high risk of ischemic stroke. The administration of vitamin B₆ will provide pyridoxal 5'-phosphate to the systemic circulation after metabolism in the liver.

Applicants argue vitamin B₆ is pharmaceutically distinct from, and not pharmaceutically equivalent to, pyridoxal-5'-phosphate, and Jacobs did not look at a therapeutically effective amount delivered as a pharmaceutical. Applicants conclude it is impossible that therapeutic levels of pyridoxal-5'-phosphate could be obtained through oral pyridoxine supplementation.

The prior art recognizes the average adult minimal requirement for pyridoxine is about 1.5 mg per day. Pyridoxine is commercially available as an oral or parenteral product. A desired dosage may be added to an enteral formulation. The interconversion of the three forms of vitamin B₆, pyridoxine, pyridoxal and pyridoxamine, is a dynamic process. All three forms are readily absorbed from the gastrointestinal tract, but pyridoxal phosphate accounts for at least

60% of circulating vitamin B₆. It is thought to be the primary form that crosses cell membranes. Further, when a documented reduction in pyridoxal phosphate concentration occurs, as in women who are pregnant or who are taking oral contraceptives, the recommended supplementation of vitamin B₆ appears to be sufficient to meet the requirements of such individuals. Pyridoxine elicits no outstanding pharmacodynamic actions after either oral or intravenous administration according to Goodman & Gilman when administered in nontoxic amounts.

Therefore, Applicants' argument is not found persuasive. The rejection of record of claims 1 and 5-11 under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al., Stroke, in view of Goodman & Gilman, is maintained. The administration of vitamin B₆ will provide pyridoxal 5'-phosphate to the systemic circulation after metabolism in the liver. Jacobs provides motivation to administer vitamin B₆ because low dietary levels are associated with an increased risk of ischemic stroke. The determination of an optimal dosage is a parameter that is well within the purview of those skilled in the art through no more than routine experimentation.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event,

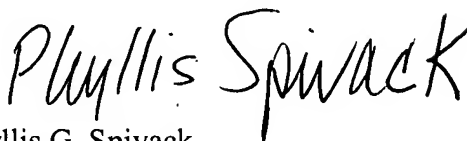
however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 28, 2007


Phyllis G. Spivack

**PHYLLIS SPIVACK
PRIMARY EXAMINER**